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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/746,990

Applicant(s)

WU ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,6-10,13,15-17 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-10,13,15-17,20-25,27 and 28 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 limits the medical device of claim 1 to a connector housing or a luer lock. However, claim 1 requires a medical device having a first and second surface which are rotatable with respect to one another about a pivot point. As set forth in the previous office action, neither a connector housing nor a luer lock rotate about a pivot point and have a contact area adjacent the pivot point. A luer lock and connector housing only rotate with respect to the central axis of the device, not about a pivot point having a contact area therebetween.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

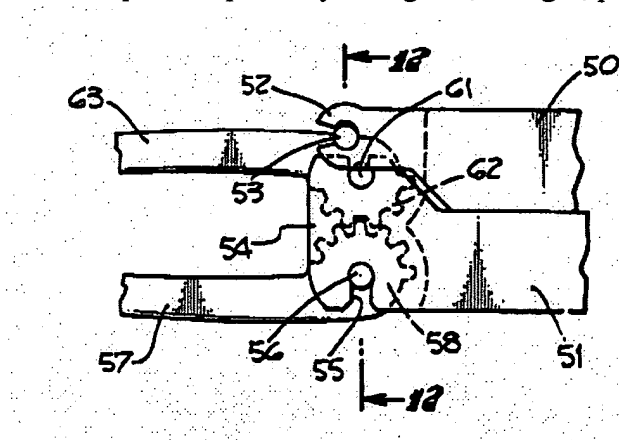
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1744

4. Claims 1, 4, 6, 13, 15, 21, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Markham (U.S. Patent No. 5,176,699).

Markham teaches a medical device (forceps) comprising a first surface 58 and a second surface 62, the first and second surfaces being adjacent to each other in facing relationship and being rotatable with respect to one another about a pivot point (point of contact within yoked head 54) and having a contact area therebetween. The contact area comprises a plurality of regular, straight, parallel, grooved projections/lines (e.g. gears)



on both the first and second part. With respect to the limitation that the projections are “adapted to allow a fluid to flow around said projections” or “adapted to promote flow of fluid between the surfaces at the contact area,”

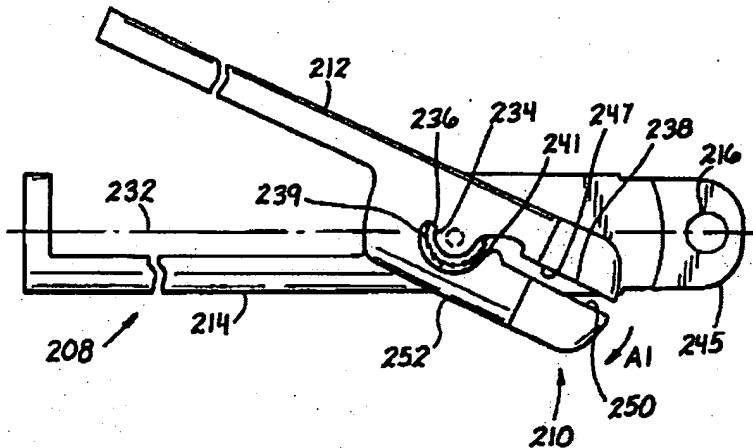
it has been held that the recitation that an element is “adapted to” perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The Examiner submits that the “projections” of Markham will permit fluid flow therebetween.

5. Claims 1, 4, 6, 13, 15, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sackier et al. (U.S. Patent No. 5,776,146).

Sackier et al. discloses a medical device (surgical clamp/holder) having a first surface 241 and a second surface 239, the first and second surfaces being adjacent to each other in facing relationship and being rotatable with respect to one another about a pivot point and having a contact area therebetween at the pivot. The contact area comprises a

Art Unit: 1744

plurality of regular, straight, parallel, grooved projections/lines at 239. As set forth above, with respect to the limitation that the projections are "adapted to allow a fluid to



flow around said projections" or "adapted to promote flow of fluid between the surfaces at the contact area," it has been held that the recitation that an element

is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. The Examiner submits that the "projections" of Sacker et al. will permit fluid flow therebetween.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1744

7. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markham or Sackier et al..

Although not specifically disclosed by Markham and Sackier et al, it is deemed obvious to fabricate the medical devices from non-reactive metals (e.g. surgical grade stainless steel) and polymers, as is well-known in the art.

8. Claims 16, 17, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schad (WO 96/30058) in view of either Markham or Sackier et al..

Schad teaches a method of cleaning and disinfecting surgical forceps within a chamber, wherein the forceps are contacted with a cleaning/disinfecting fluid within a vessel 4 while being moved. The method achieves a surgical instrument suitable for reuse. Although Schad does not disclose that the forceps have a plurality of projections on a contact area at the pivot point, both of Markham and Sackier et al. evidence that this is the common configuration found in medical forceps. Therefore, it would have been obvious to employ the method of Schad to clean and disinfect the surgical forceps of the prior art, as it has been shown to be effective in cleaning forceps.

With respect to circulating the fluid in the vessel 4, Schad discloses that the fluid is hot steam of about 120 °C (col.4, lines 1-5). It would have been obvious to circulate the steam within the vessel during the step of contacting, in order to equalize the sterilization temperature within the vessel thereby assuring that the forceps achieves the sterilization temperature. Moreover, with respect to flowing the fluid around the projections, Schad teaches that the hot steam penetrates deep into a surgical instrument and reaches the most inaccessible places thereof. See page 2, lines 25-35. Thus, such a step is intrinsic in the method of Schad.

Art Unit: 1744

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schad and either Markham or Sackier et al. as applied to claim 16 above, and further in view of Moyers (US 6,090,213).

The combination of Schad with either of Markham or Sackier et al. fails to teach reducing a pressure in the vessel. Moyers, however, discloses a method of cleaning endoscopic implements wherein after cleaning a vacuum is pulled on the chamber in combination with the application of hot air in order to remove all moisture from the implements. See col.3, line 31 to col.4, line 5. Since Schad discloses that the sterilized instruments are dried by application of hot air, it is deemed obvious to also apply a vacuum, in the manner of Moyers in order to shorten the drying time.

***Allowable Subject Matter***

10. The indicated allowability of claim 13 is withdrawn, as applicant amended the claim canceling the previously indicated allowable subject matter.

11. Claim 26 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: In the medical device of Markham, both the first and second part carry grooves. However, the grooves on the first part are not in registry with the grooves in the second part, since the first and second part form a gear. In a gear, the grooves on one part must register with the projections of the second part.

***Response to Arguments***

13. Applicant's arguments filed 14 October 2005 have been fully considered but they are not persuasive.

14. Applicant argues that the devices of Sackier et al. and Markham have "gears in which the surfaces of the devices which are in facing relation do bear projections." The Examiner respectfully disagrees with applicant's assessment of the Sackier et al. and Markham references. In the Examiner's interpretation of the references, the gears themselves are the projections on the surfaces.

***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



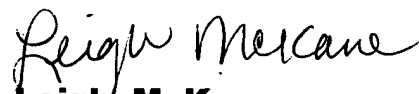
Art Unit: 1744

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275.

The examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on 571-272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
4 January 2006